101. The device of claim 88, wherein the capture reagent is an analyte-specific antibody immobilized in the detection zone.

E6 (cont'd)

102. The device of claim 88, further comprising a non-specific control reagent disposed in a control zone of the dry porous carrier, said control reagent capturing the labeled binding reagent to produce a detectable product in the control zone in the presence or absence of analyte in an applied sample.

REMARKS

This paper is in supplementation to the amendments filed November 4, 2002, December 23, 2002 and March 6, 2003 for the above-captioned application.

Claims 44 and 64 are amended to add missing punctuation to line 4 of the claims.

Amendments are made to claims 84 and 88 to delete the word "dry" which was inadvertantly not deleted in the prior amendment.

Claim 87 has been amended to make it fully clear that mobilization of the labeled binding reagent occurs when the binding reagent is wetted.

Claims 89-102 are added by this amendment. The Commissioner is authorized to charge the fees for these additional claims to Deposit Account No 15-0610. Claims 89 and 90 correspond to claims 36 and 37 but are dependent on claim 84. Claims 91 and 96 correspond to claim 45, but are dependent on claims 84 and 88, respectively. Claims 92 and 97 correspond to claim 35, but are dependent on claims 84 and 88, respectively. Claims 93 and 98 define the device as a lateral flow device (substantially planar flow path) consistent with the disclosure and the drawings of the application. Claims 94 and 99 add the overlap limitation which was in the claims of the issued parent case. Claim 100 corresponds to claim 86. Claim 101 corresponds to claim 85. Claims 95 and 102 correspond to claim 42, but are dependent on claims 84 and 88, respectively.

Applicants enclose herewith a PTO-1449 form and a copy of European Patent Publication 0 323 605A2. This publication is not itself prior art with respect to this application since it was

published after the British Priority date of February 17, 1989 claimed by Applicants. However, the European application cites two US applications as priority applications, and thus may be of interest to the Examiner. To Applicant's knowledge, no patents have issued on these US applications. However, US Patent No. 5,075,078 incorporates the US applications by references. The filing date of this '078 Patent is October 5, 1989, after Applicants' British date. Thus, this reference is not sufficient to make the disclosure of these applications prior art under 35 USC § 102(e).

Because of the relative filing dates, the '605 publication was effective prior art in Europe under Article 54(3) EPC against the European counterpart of the present application only in regards to novelty (anticipation) and not for purposes of obviousness. As the Examiner may be aware, there is no statutory duty of candour in respect of the European Patent Office. Hence, there is no specific obligation to disclose relevant prior art to the European Examiner. In view of the '605 reference, however, in a letter dated 25 August 1995, the applicants did not approve the text referenced in the earlier Rule 51(4) Communication and voluntarily re-opened examination of their application at the same time presenting new claims to the European Patent Office. (Exhibit A) In a reply to that letter, the European Patent Office accepted the applicants' reasoning and the newly presented claims without further argument, although some minor amendments were required to both the claims and the description. Thus, the European counterpart of the parent application was eventually granted with the new claims as European Patent No. EP 0383619 B on 23 April 1997.

Claims 89-98 are added to provide claims including the distinction added in the corresponding European Application, as well as other distinctions between the claims of this application and the disclosure of the European '605 Application should it prove in any subsequent litigation that the European '605 Application reflects provable prior art under 35 USC § 102(g).

Entry of this amendment and consideration of claims 26-97 are respectfully requested.

Respectfully Submitted,

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MARKED UP COPY OF AMENDED CLAIMS

44. (amended) The device of claim 26, wherein the device further comprises a second immobilized specific binding reagent which binds specifically to a second analyte, said second immobilized specific binding reagent being immobilized in a second detection zone on or in the dry porous carrier; and a second labeled specific binding reagent comprising a particulate label portion and a binding portion specific for the second analyte, wherein said second labeled specific binding reagent and said second immobilized specific binding reagent combine with the second analyte, if present, to form an immobilized and directly-detectable product in the second detection zone, said second labeled specific binding reagent being contained in the macroporous body.

63. (amended) The device of claim 45, wherein the device further comprises a second immobilized specific binding reagent which binds specifically to a second analyte, said second immobilized specific binding reagent being immobilized in a second detection zone on or in the dry porous carrier; and a second labeled specific binding reagent comprising a particulate label portion and a binding portion specific for the second analyte, wherein said second labeled specific binding reagent and said second immobilized specific binding reagent combine with the second analyte, if present, to form an immobilized and directly-detectable product in the second detection zone, said second labeled specific binding reagent being contained in the macroporous body.

84. (twice amended) A device for analyzing a liquid sample suspected of containing an analyte, comprising a housing, having disposed therein:

(a) a porous carrier comprising a detection zone;

(b) a capture reagent effective to capture analyte in the detection zone, said capture occurring after the liquid sample has been applied to the device if said analyte is present in the liquid sample;

(c) a labeled binding reagent comprising a particulate label portion and a binding portion, wherein said labeled binding reagent and said capture reagent combine with analyte, if present, to form an immobilized and directly-detectable product in the detection zone; and

(d) a macroporous body disposed such that a liquid sample applied to the macroporous body will flow along a flow path extending from the macroporous body and into the [dry] porous carrier at a location separated from the detection zone, wherein the macroporous body contains the labeled binding reagent, said labeled specific binding reagent being freely mobile within the macroporous body when the macroporous body is wetted with the liquid sample.

87. (twice amended) In a device for detection of an analyte in a sample, in which a liquid sample is applied to a porous carrier comprising a detection zone and a sandwich complex is formed in the detection zone when analyte is present, said sandwich complex comprising a labeled binding reagent, the analyte and an immobilized capture reagent, the improvement wherein the device further comprises a macroporous body disposed such that a liquid sample applied to the macroporous body will flow along a flow path extending from the macroporous body and into the porous carrier at a location separated from the detection zone, wherein the macroporous body contains the labeled binding reagent, said labeled binding reagent being freely mobile within the macroporous body when the labeled binding reagent in the macroporous body is wetted with the liquid sample.

88. (amended) A device for analyzing a liquid sample suspected of containing an analyte, comprising:

(a) a porous carrier comprising a detection zone;

(b) a capture reagent effective to capture analyte in the detection zone, said capture occurring after the liquid sample has been applied to the device if said analyte is present in the liquid sample;

(c) a labeled binding reagent comprising a particulate label portion and a binding portion, wherein said labeled binding reagent and said capture reagent combine with analyte, if present, to form an immobilized and directly-detectable product in the detection zone; and

(d) a macroporous body disposed such that a liquid sample applied to the macroporous body will flow along a flow path extending from the macroporous body and into the [dry] porous carrier at a location separated from the detection zone, wherein the macroporous body contains the labeled binding reagent, said labeled specific binding reagent being freely mobile within the macroporous body when the macroporous body is wetted with the liquid sample.

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Our Ref: DJB/VW/P3073 EPO Date: 25 August 1995

BY FACSIMILE

Dear Sirs,

European patent application No. 90301697.0-2116
(Unilever PLC et al)

We refer to the communication dated 27th February 1995 pursuant to Rule 51(4) EPC on this application. The period for response has been extended to a total of 6 months.

The applicants regret that they are not able to approve the accompanying text.

The applicants wish to draw attention to the disclosures in EP-A-323605 published on 12 July 1989. This was after the priority date (17 February 1989) claimed in the present application. EP-A-323605 is citable under Article 54(3) EPC. This document has not been cited or considered previously in relation to the present application.

EP 323605 describes assay devices having "an application pad" containing a labelled reagent. Amongst the materials from which the application pad can be made is "porous polyethylene frit". Example 3 describes a specific embodiment in which the application pad material is "porous polyethylene (4mm x 10mm x 1.5mm rectangles of Porex material, Porex Technologies, Fairburn, G A)".

After detailed consideration of the disclosure in EP 323605, the applicants have come to the conclusion that the specific embodiment as described in terms of the application pad material and its function, correspond exactly to the macroporous body (113) as specifically described in the Example in the present application. Although the terminology used in the two specifications is different, the knowledgeable reader will recognise that the materials described are identical.

Accordingly, the applicants believe that the disclosures of EP 323605 constitute an anticipation of the main claim currently

in the application.

We request that the examination be re-opened. We enclose a new set of claims for the Examiner's consideration. We have added to claim 1 the content of previous claim 16 which refers to a porous receiving member (106) to which the liquid sample can be applied and from which the sample can permeate into the porous carrier. The disclosure in EP 323605 appears to contemplate that the "application pad" acts in effect as the sample receiver. It is clear from the disclosures in applicants' specification that the porous receiving member (106) contemplated therein has a very specific function in that it receives the sample and acts as a reservoir of sample liquid for the entire device. This concept does not appear to be disclosed in EP 323605.

We have added an additional claim 15 in which the porous receiving member (106) is defined as being made of material having unidirectional porosity. This is disclosed in our application at page 11 lines 1 to 4.

Some minor renumbering has been necessary for other claims.

If, after considering the disclosures of EP 323605, the Examiner is happy that these revised claims are acceptable, we shall be pleased to provide appropriate substitute pages for the specification.

The applicants regret that this complication has arisen on this application, but the full significance of the disclosures in EP 323605 have only recently been recognised.

Yours faithfully,

D J Butler
General Authorisation No. 170

DJB3032